TRIPS AGREEMENT AND LEGAL CHANGES IN INDIAN PATENT LAWS

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ABSTRACT

The TRIPS agreement is a minimum standards agreement, which permits members to offer more extensive protection of intellectual property. The Paris Convention, the Berne convention, international convention for the protection of Performers, generators of phonograms and Broadcasting Organization (Rome Convention), and the Treaty on intellectual property in respect of integrated Circuits (IPIC Treaty) Articles 3, 4 and 5 comprise the fundamental rules on national and most favored- nation treatment of foreign nationals, which are common to all categories of intellectual property covered by the Treaty.

The TRIPS requires Members countries to make patent available for any invention, whether products or processes, in all fields of technology without inequity, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patent be available and patent rights enjoyable without inequity as to the place of invention and whether products are imported or locally generated. The application for patent shall be in the appropriate prescribed form only. The application shall be either in English or in Hindi.

The new set of challenges stem from the deeper implications of the imminent product patent regime. With the exception of a few, most Indian pharma companies are unfamiliar with the nuances of complex patent prosecution strategies. The research-based pharmaceutical companies, on the other hand, have firsthand knowledge of successfully designing and implementing, sophisticated patent prosecution strategies. Therefore, the first hurdle for the Indian pharma industry is unevenness in the domain knowledge on patents. One of the ways to overcome this is to learn the use of patents as a business tool. The unrealistic defence against the global norms on patents is perhaps the most critical post-TRIPS challenge faced by the Indian pharmaceutical industry.

This section attempts to analyze the implications of the TRIPS compliant patent regime.

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The key issues taken up in this section are

a) The scope and extent of patentability of pharmaceutical products;

b) Ever greening - the patent term extension strategies; and

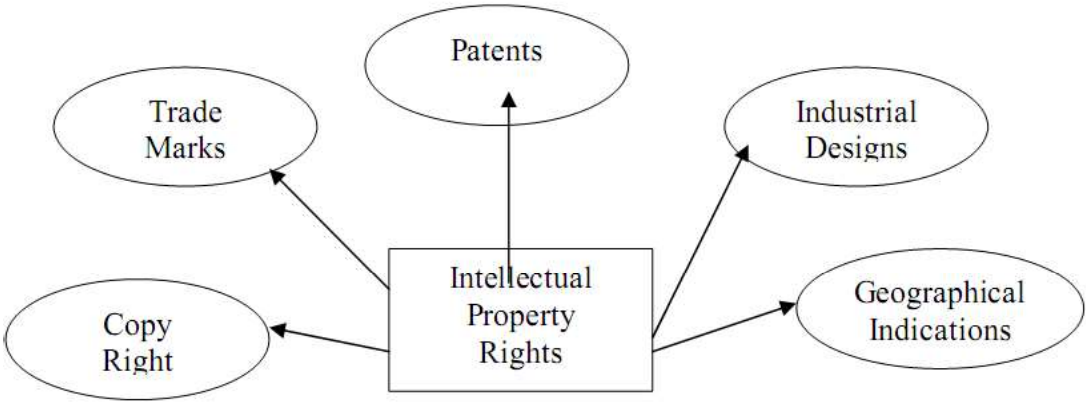
c) Implications of Compulsory Licensing provisions.

Key words

IPRs-Intellectual property Rights ,**TRIPS-** Trade Related aspect of intellectual property, **WIPO-** world intellectual property organization, **WTO** – World Trade organization, **IPIC**- intellectual property in respect of integrated Circuits , **MFN-** Most favored Nation , **EMR** - Exclusive Marketing Rights , **PCT** - Patent Cooperation Treaty

TRIPS AGREEMENT AND LEGAL CHANGES IN INDIAN PATENT LAWS

The TRIPS agreement is a minimum standards agreement, which permits members to offer more extensive protection of intellectual property if they so wish. Members are left free to verify the appropriate method of implementing the stipulations of the Treaty within their own legal system and practice.[136]



As in the main- existing intellectual property conventions, the basic obligation on each member country is to accord the treatment in regard to the protection of intellectual property offered for under the Treaty to the persons of other members.

Article 1.3 defines *who these persons are.* These persons are referred to as "nationals" but comprise persons, natural or legal, who have a close attachment to other Members

[136] Ruth L. Okedji, 'The International Patent Systems: Limitations, Exceptions, and Public Interest Considerations for Developing Countries, UNCTD Project on IPR and Sustainable Development, March 2006

without necessary being nationals. The criteria for determining which persons must thus benefit from the treatment offered for under the Treaty are those laid down for this purpose in the main pre-existing intellectual property conventions of WIPO, applied of course with respect to all WTO members whether or not they are party to those convention.

These conventions are the Paris Convention, the Berne convention, international convention for the protection of Performers, generators of phonograms and Broadcasting Organization (Rome Convention), and the Treaty on intellectual property in respect of integrated Circuits (IPIC Treaty) Articles 3, 4 and 5 comprise the fundamental rules on national and most favored- nation treatment of foreign nationals, which are common to all categories of intellectual property covered by the Treaty.

These obligations cover not on the substantive standards of protection but also matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in the Treaty.

While the nation treatment clause forbids inequity between a member's own nationals and the nationals of other members, the most-favored -nation treatment clause forbids inequity between the nationals of other members. In respect of the national treatment obligation, the exception permitted under the pre-existing intellectual property conventions of WIPO are also permitted under TRIPS.

Where these exceptions permit material reciprocity, a consequential exception to MFN treatment is also permitted (e.g. comparison of terms for patent protection in excess of the minimum term required by the TRIPS Treaty as offered under Article 7(8) of the Berne convention as incorporated into the TRIPS agreement). Certain other limited exceptions to the MFN obligation are also offered for.

The general goals of the TRIPS Treaty are contained in the preamble of the Treaty , which regenerates the basic Uruguay Round negotiating objectives maintained in the TRIPS area by the 1986 Punta del Este Declaration and the 1988/89 Mid-Term Review. These objectives comprise the reduction and impediments to international business, promotion of effective and adequate protection of intellectual property rights, and ensuring that measures and processes to enforce intellectual property rights do not themselves become barriers to legitimate business. These objectives should be read in conjunction with Article 7, entitled "objectives" according to which the protection and enforcement of intellectual property rights should contribute to the promotion of

technological innovation and to the transfer and dissemination of technology, to the mutual advantage of generators and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

The TRIPS Treaty requires Members countries to make patent available for any invention, whether products or processes, in all fields of technology without inequity, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patent be available and patent rights enjoyable without inequity as to the place of invention and whether products are imported or locally generated (Article 27.1)

There are three permissible exceptions to the basic rule on patent ability. One is for invention contrary to "order public" or morality: this explicitly comprises invention dangerous to human, animal or plant life or health or seriously prejudicial to the environment. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of" order public" or morality (Article 27.2)

The second exception is that members may exclude from patent ability diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27.3(a).

The third is that members may exclude plants and animals other than micro- organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

However, any country excluding plant varieties from patent protection must offer an effective "sui generic" system of protection. Moreover, the whole stipulation is subject to review four years after entry into force of the agreement. [Article 27.3(b)].

The exclusive rights that must be conferred by a product patent are the ones of making, using, offering for sale, selling, and importing for these purposes. Process patent protection must give rights not only over use of the process but also over products obtained directly by the process. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts (Article 28).

Members may offer limited exceptions to the exclusive rights conferred by a patents, offered that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner,

taking account of the legitimate interests of third parties (Article 30).[137]

The term of protection available shall not end before the expiration of a period of 20 years counted from the filing date (Article 33)

Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require to indicate the best mode for carrying out the invention known to the inventor known to the inventor at the filling date or, where priority is claimed, at the priority date of the application (Article 29.1).

If the subject-matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patent process, where certain conditions indicating likelihood that the secured process was worn are met (Article 34)

Compulsory licensing and government use without the authorization of the right holder are permitted, but are made subject to conditions aimed at protecting the legitimate interests of the right holder. The conditions are mainly contained in Article 31.

These comprise the obligation, as a general rule, to grant such license only if an unsuccessfully attempt has been made to acquire a voluntary license on reasonable terms and conditions within a reasonable period of time; the requirement to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the license and a requirement that decisions be subject to judicial or other independent review by a district higher authority.

Certain of these conditions are relaxed where compulsory licenses are employed to remedy practices that have been maintained as anticompetitive by a legal process. These conditions should be read together with the related stipulations of Article 27.1, which required that patent rights shall be enjoyable without inequity as to the field of technology, and whether products are imported or locally generated.

The application for patent shall be in the appropriate prescribed form only. Separate forms are prescribed for filing the application by the true and first inventor, and for the assignee or legal representative of the inventor. The application and all its enclosures shall be filed in triplicate.

The fees shall be paid along with application. And the controller will not take any action

[137] Andrew F. Christie, 'Intellectual Property and Intangible Assets: A Legal Perspective' in Bosworth D. and Webster E. (eds), The Management of Intellectual Property, 2006, Edward Elgar, Cheltenham, UK and Northampton, USA

on the application unless the fees are received by him.

Where the application is sent by post it shall be sent by the Registered post acknowledgement due. Unless the acknowledgement is generated the controller will not accept any other proof of service. The application shall be accompanied by stipulation specification or complete specification as the case may be.

If the applicant is the assignee or legal representative, proof of applicant's right to make the application shall be filled along with the application for patent or within 3 months from the date of application. In all the cases the application should contain the name of the true and first inventor and applicant must also say that he is in possession of the invention. The application shall be confined to one invention only. The application shall be either in English or in Hindi.

As with the stipulation specification, complete specification will also commence with the title, and a paragraph may be devoted for defining and explaining various terms worn in the specifications. The description of the invention which follows must be full and shall give all details. Simple and clear language shall be worn and ambiguity should be avoided. The description shall follow a sequence of either events, thoughts, experiments or the progression of the invention.

It is necessary that a separate paragraph is set apart and devoted to the methods and processes of working the invention. Insufficient description, lack of bona fids or avoidance to disclose fully will result in the rejection of application for patent. If there are different methods of working the patent, they may be described and comprised in the complete specification and the applicant is entitled to comprise all of them in his claims as covered with in the monopoly. The final paragraph in the complete specification shall be exclusively devoted to the claims in relation to which the applicant claims monopoly and claims that by virtue of this monopoly none else should be entitle to use or adopt the patent.

After Controller has rendered his decision and ordered the grant of patent, the applicant has to make an application for the issue of patent and for sealing it. Such an application can be filed within six months from the date of the decision of the controller or within such extended time the controller may grant. On receipt of such request from the applicant, the controller will register the patent in the Register maintained at the office of the controller of patents and grants the patent with a number which was originally allotted to it on the date of the acceptance of the completed specification and dated also the same date on which it was numbered. The controller will on the date of the issue of patent, seal the patent. Therefore, the patent will bear the number and date on which the

complete specification is accepted and the sealing date is the date on which the patent is registered and sealed.

A key international convention relating to patents is the Paris Convention for the Protection of Industrial Property, initially signed in 1883. The Paris Convention sets out a range of basic rules relating to patents, and although the convention does not have direct legal effect in all national authorities, the principles of the convention are incorporated into all notable current patent systems.

The most vital aspect of the convention is the stipulation of the right to claim priority: filing an application in any one member state of the Paris Convention preserves the right for one year to file in any other member state, and receive the benefit of the original filing date. Another key treaty is the Patent Cooperation Treaty (PCT), administered by WIPO and covering more than 140 countries.

A patent is requested by filing a written application at the relevant patent office. The person or company filing the application is referred to as "the applicant". The applicant may be the inventor or its assignee. The application contains a description of how to make and use the invention that must offer sufficient detail for a person skilled in the art (i.e., the relevant area of technology) to make and use the invention.

In some countries there are requirements for providing specific information such as the usefulness of the invention, the best mode of performing the invention known to the inventor, or the technical problem or problems solved by the invention. Drawings illustrating the invention may also be offered. The application also comprises one or more claims that define what a patent covers or the "scope of protection".

The date of patent is relevant for purposes of calculating the term of the patent. The fourteen year term of patent commences from the date of patent. This also is the date relevant for purposes of calculating the amount of renewal fees which is business upwards for each successive year and the due dates for payment of renewal fees.

The date of sealing is relevant for purposes of calculating the five year or seven year term of the patent which is the granted in relation to the processes of articles of food and drugs. The date of sealing is relevant also for purposes of determining the time after which compulsory licenses of right can be granted

The first obligation is that the patent holder must work the patent. He should thus, fulfill the primary object of the grant of patent. He should act as model for further invention. The next obligation is to pay renewal fees as prescribed in accordance with the scale on due dates every year. The third obligation of the patent holder is that he should report to

the controller the progress of the working of the patent.

Renewal fees are not payable for the period during which a direction given by the controller to keep the patent secret in view of the security requirements, remains in force. If the direction is revoked in any year irrespective of the time at which the order of revocation was issued, renewal fees shall have to be paid for the full year. If in any year the patent holder fails to pay the renewal fees in time he may get extension up to six months and pay the renewal fees accordingly. If the renewal fees are not paid even after the period is extended, the patent ceases to have effect from the date when the renewal fee first fell due and not on the date when the extended period expires.

The patent office at Calcutta will maintain a Register of patent. It contains all relevant particulars about the patent as and when they are registered. All the additional entries relevant to the registration and all changes and amendments will be duly entered so that the register reflects the position up to date.

Rights of the patent holder are the rights of monopoly exclusive to him in the patent. He, who breaches the monopoly, is said to infringe the rights of the patent holder. The rights of monopoly granted to the patent holder consists in his exclusive right, to make, use, exercise, sell or distribute the articles manufactured in accordance with the patent or manufactured in accordance with the patent process. Nobody else can use patented invention or patented process for manufacturing the articles or substances.

A person who uses the patented invention or a patented process or the person who generates the articles and substances, for which there exists a patent, commits violation. A person or institution which uses the patented invention for research purposes does not commit any violation. Violation of patent is not a criminal offence. The infringer is not liable to be prosecuted in any criminal court.

The patent holder cans sure the infringer for permanent injunction. He can also ask for ex parte interim injunction on the date of filing the suit which if granted will be in force initially for a period of one month and thereafter continued or withdrawn in accordance with the orders that may be made by the court. The patent holder can ask for damages or for a direction to render an account for profits.

As a matter of fact the suit is only one in which all the relief can be asked for comprising delivery of and destruction of infringed articles. The act does not require that any previous notice is necessary before action is taken against the infringer. If there are circumstances which warrant the issue of notice hopefully with a view that the defendant

may settle the matter out of court, a notice may be issued. Where injunction is an immediate necessity there should not be any delay in filling the suit.

The WTO's agreement on TRIPS makes it mandatory for all countries to establish standards for intellectual property protection. This Treaty came into effect on1995 of all developing nations comprising India, needed to fulfill the above requirements by 2000. While the developed countries were to implement this requirement by 1996, the schedule for the least developed ones gave then time till 2005.

The TRIPS solution suggests a wonderful *new market will open up for nations like India, South Africa, Brazil and china* which have domestic manufacturing capacity in pharmaceuticals. There are so many safeguards that few compulsory licenses will actually be worn not to mention the delivery and government problems that will plague exporters from India. It could make India and other developing countries think a big victory has been wrested & thus deflect attention from more important issues like agriculture.

The criticism centers especially on the re-introduction of product patents for foods, drugs and chemicals. A substantial part of the criticism is based on misconceptions. This is particularly true of claims that the Indian drug industry has been able to bring down the price of medicines as a result of the act, which deleted the stipulations for grant of product in the case of foods, drugs and chemicals alone.

The patent Act 1970, granting only process patent for drugs, enabled even small and medium Indian companies to generate indigenous versions of drugs developed abroad, especially in the U.S. and Europe and even exports them. The low price of Indian drugs was because the material cost of the final product was very low, compared to the costs involved in the development of drugs.

Development costs comprise not just the wages of medical and scientific manpower involved in research, but also the infrastructure required for experimentation on animals and humans over a long period before a new drug is ready. This is followed by a lengthy and rigorous process of approval by the regulatory authorities.

It is in the nature of chemical products that their composition can be easily known and they can then be made through alternative processes. Any company that makes a drug developed and patented by somebody else but uses another process avoids the bulk of the development costs and thus able to generate and sell it at a low cost.

The patent act, 1970, reflected the experience of the colonial era. The British rulers has worn the Indian patent and Designs Act, 1911, to force products comprising drugs on this country - encouraging imports from Britain and discouraging manufacture in India.

At present, there is enormous scope for investment of capital, both indigenous and foreign for manufacturing within India. What's more, India's vast scientific man power can be harnessed to make the industry an innovator of new drugs at low cost. This will help the Indian drug industry take advantage of product patents, instead of making it dependent on the development of drugs abroad for producing copies. The latter option, supported by 1970 Act is economic, which a nation can embrace only at the risk of undermining its own technological potential.

Among the objections to the restoration of product patent for drugs are allegations that drug multinationals indulge in monopoly practices and those they exaggerate the cost of product development. The power of monopolistic companies is controlled by the Government through anti- trust legislation, price regulation, etc. The limited monopoly that a patent entails is a grant from the State to any innovator - Individual or business or institution.[138]

The patentee is entitled to compensation from anyone, comprising a big company or multinational company that puts his invents or innovation to commercial use. Thus, the patent monopoly granted by the Intellectual Property right (IPRs) system is not only different from but also in a sense a counterweight to the power of big firms, especially in a developing country. Also, if the cost of research and development is exaggerated as well develop new drugs at non-exaggerated costs and capture markets.

However, one valid objection to the reform of the Indian Patent Rule is the introduction of Exclusive Marketing Rights (EMRs) in the period of transition (10 years from 1995 to the product patent regime) in tune with the TRIPs agreement.

The new patent ordinance expands the patent ability criteria from drugs and agro-chemicals to other fields of technology, such as embedded software. One of the major stipulations introduced was regarding grant of compulsory license, which means that Indian manufacturers will be able to manufacture and export patented medicines to countries, which have insufficient or no manufacturing capacity.

The introduction of a stipulation to enable grant of compulsory license for export of medicines to the countries that have insufficient or no manufacturing capacity to meet emergent public health situations, is in accordance with the Doha Declarations on trade Related Intellectual Property rights (TRIPs) and public health.

[138] Part II, Section I, Art. 9 of the TRIPS agreement states that the member states shall comply with the provisions of the Berne Convention; the provisions listed above are the general categories to which patent protection extends under the Berne Convention, Article 2(1)

The ordinance seeks to strengthen opposition proceedings by permitting for both pre-grant and post-grant opposition. Pre-grant opposition can be filed any time after publication. While earlier there was no time frame, the ordinance highlights that if a pre-grant application is filed close to a patent being granted then, in certain cases, it has to be cleared within 90 days. Rationalization of stipulations relating to time-lines has been done with a view to introducing flexibility and reducing the processing time for patent applications, and simplifying and rationalizing processes.

The Ordinance also seeks to simplify and rationalize the time-frame for process of patents. The time limit for giving requests for examination has been reduced to 36 months from 48 months earlier.

Another important stipulation made in the Act, is that the patent will be available from the day when the patent is granted and not when it is published. This means that many Indian Companies will be saved from violation cases by the multinational majors, who might get patents for drugs which Indian companies are selling.

What is most likely to happen is that the companies that have the patent for a particular drug may force the company producing a generic version of the same to stop production but they cannot bring a libel suit on the generic generator retrospectively. Another important stipulation relates to the extension of patents in case of incremental innovations. It means that the companies, which come up with new usage of the same product may not get patent for the new usage. Security stipulations are also tightened, particularly, for dual-use patent applications. Such patents will now scrutinized by the patent office. While software would continue to be patent-secured, embedded software that has technical applications can now be patented.

Thus, patent applications based on collaborative research and research work being done in India has to be filed in India first, comprising the PCT. Some controversy arises related to the product patent regime. From an academic Point of view, product patent helps countries to develop and be self-reliant. But, from a humanitarian perspective, it will adversely defect and life of poor people in developing countries. The argument from the product patent lobby is that most of the existing drugs became generic, so the regime won't affect much. Instead of reverse engineering or copying existing foreign drugs, Indian companies should offer more money for research and development. The government should also support more R&D, which helps increase employment opportunities.

Inventions whose primary or intended use or commercial exploitation is contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment are not patentable.

The phrase 'serious prejudice to human, animal or plant life or health or to the environment' was introduced to accommodate and clarify the expanding meaning of the words 'public order or morality'. The jurisprudence of the EPO interpreting the scope and meaning of the words 'public order or morality' will be relevant as this stipulation is similar to art 53(a) of the EPC.

Generally an idea or a discovery cannot be a subject matter of a patent. A practical application of an idea or a discovery can, however, qualify for a patent. Such a discovery will be patentable even though the practical application of the discovery is inherent in the discovery itself or becomes obvious once the discovery is made.

Such a patent should claim the practical application of the discovery as an invention. A method of identifying diamonds by means of photographic records of their X-ray diffraction patterns was held to be a patentable invention.

Thus, mere discoveries or ideas cannot be the subject matter of a patent, but discoveries or ideas which have a technical aspect or make a technical contribution will be patentable.

October 2004 the general assembly of the world intellectual property organization (WIPRO) decided to consider what a development- oriented intellectual property regime might look like. The current rules of the international economic games reflect the interests of the advanced industrial countries- especially of their big corporation- more than the interests of the developing world. Without intellectual property protection, but there are high costs associated with intellectual property. Ideas are the most important input into research, and if intellectual property slows the capability to use other' ideas, then scientific and technological progress will suffer.

By contrast, an intellectual property regime rewards innovators by creating a temporary monopoly power, permitting them to charge far higher prices than could if there were competition. In the process, ideas are disseminated and worn less than they would be otherwise. The economic rationale for intellectual property is that faster innovation offsets the enormous. Costs of such inefficiencies. But it has become increasingly clear that excessively strong or badly formulated intellectual property rights may actually impede innovation - and not just by increasing the price of research.

Unfortunately, the trade negotiators who framed the intellectual-property agreements of the Uruguay business round of the early '90s (TRIPS) were either unaware of all of this, or more likely, uninterested. Intellectual property is important, but the appropriate

intellectual property regime for a developing country is different from that for an advanced industrial country. The TRIPs scheme failed to recognize this. In fact, intellectual property should never have been comprised in a trade treaty in the first place, at least partly because its regulation is demonstrably beyond the competency of business negotiators.

Besides, an international organization already exists to protect intellectual property. Hopefully, in WIPO's reconsideration of intellectual property regimes, the voices of the developing world will be heard more clearly than it was in the WTO negotiations; hopefully, WIPO will succeed in outlining what a pro-developing intellectual property regime implies; and hopefully, WTO will listen; the aim of business liberalization is to boost development, not hinder it.

The patent (Amendment) Act, 2005 is presently in force. Subsequently, the central Government amended the patent Rules, 2003 and the rules were called the patent (Amendment) Rules, 2005. By a publication dated June 2005 in the gazette of India, further amendments to the rules were published, called the patent (Second Amendment) Rules, 2005.

With regard to the examination of the application and time for placing the application in order, section 11B of the patent (Amendment) Act, 2005 stipulates that the application will tested only after filling the request for examination. Rule 24B prescribes various time limits for making the request. The Rule 24B (1)(i) also stipulates that the request for examination can be filed only after the publication of the application but within 36 months from the date of priority or the dale of filing of the application, whichever is earlier.

On the request for examination, according to the proposed amendment to Rule 24B (1)(v), in the cases of applications filed before January 1, '05, the time limit for filing a request for examination shall be the period specified under section 11B before the commencement of the patent (Amendment) Act, 2005.While appreciating the amendments proposed, It would be appropriate if the extract period was stipulated in the rule itself, instead of making a reference as proposed. Rule 24B (4) is not clear as to the applications in respect of the period specified therein. It is presumed the applications are those which have been tested after the coming into force of the patent (Amendment) Act, 2005 and not those tested earlier. So, an order for a grant under section 21 in respect of the applications, which are tested after the amended act, shall be 9 months from the date on which the first statement of objection is issued to the applicant to comply with requirements.[139]

[139] Ibid.

The applicant has a reduced time period to place the application in order for grant, namely within 9 months from the date of the first examination report. However, an extension up to maximum of three months is available in the case of the applications in respect of which the first statement of objections has been issued after the commencement of the patent (Amendment) act, 2005.

But, this extension has to be made before the expiry of the nine- month period from the date of the first examination report. In other words, the applicant has to take a calculated risk in securing one or two months and not the maximum three months. In addition, the fees prescribed for such as extension is very exorbitant, namely, for total fees for three months, the extension is Rs 6000, in case the applicant is an individual and Rs.24,000 in case the applicant is a legal entity that is not an individual.

These stipulations are intended to expedite the grant of patent and in principle, are a good stipulation and are appreciated. It is seen that after meeting the official requirements, the applicant has to wait for a considerable length of Time to receive another official action if any, for a considerable period of time. In other words, many a time, the patent office takes away majority of the period available.

In the case of inspection and supply of published documents, in rule 27, there is a mention of "payment of fees" but the schedule does not prescribe any such fees. Hence, if any fees are to be paid, it has to be stipulated in the schedule of fees. On the other hand, if no fees are to be paid, then the above words have to be deleted. When it comes to opposition by representation against the grant of patent, in the proposed amendment to rule 55(1), no time period has been specified, though from the new Rule 55(1)a, it can be presumed that the period is six months from the date publication under section 11A.

In order to make the rule clear and precise and not leave anything to presumption, the time limit may be specified in rule 55 (1) itself. The patent (Amendment) act, 2005 also offers the constitution of an opposition Board, which will offer inputs to the controller. The Board will consist of three examiners, one of them acting as the chairman. When it comes to inspection of documents for the grant of patent, Rule 74 A, though specifies that for this, a written request has to be made along with the prescribed fees, though no fees have been prescribed. Therefore, in the schedule of fees, the prescribed fees have to be indicated. Section 153 deals with the request of information. In rule 134 (k), the words "official Gazette" should be substituted with the words" patent office journal". This amendment is required consequent to the discontinuance of the gazette of India with effect from January 1, 2005 and the publication of the patent office journal instead.

No revision of the fees prescribed has been made. Though the fees than those indicated above are to be reviewed, so that it can be justified, as the proceedings are very few and far between and further, the situation may arise due to the negligence/ default of the applicants/ agents. Therefore, the high fees may make the applicant/ agent more vigilant. A revision or fee is required.

Insofar as patent ability of chemical molecules is concerned, it has been clarified that mere discovery of a new form of a known substance which does not result in the improvement of the known efficiency of that substance is not patentable. For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, isomers, mixtures of isomers and other derivatives of known substances are to be considered to be the same substances, unless they differ vital in properties with regard to efficacy, (amendment to section 3(d) This amendment would alleviate fears amongst the Indian pharmaceutical industry and consumers with regard to the scope of product patent.

What is not novel is now made clearer. A new form of a substance is patentable only if it results in improvement of the know efficacy of such substance.

The company would first file a patent for a drug and the formulation and after sometime, a patent for a metabolite would be tiled. A metabolite is something that is generated in a patient or body after consuming the drug. Since the metabolite patent would expire much later than the original drug patent, many companies were prohibited from making a drug that would result in that particulars metabolite.

The courts did, of course intervene and now metabolites are not patentable in the US. Reading section 3(d), it could be interpreted that metabolites are patentable if they have better efficiency.

Section 92A, which was inserted by the ordinance in pursuance of paragraph 6 of the Doha Declaration on TRIPS, has been further amended. Now, compulsory license to manufacture and export the patented product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector can also be granted if such country has permitted importation of the patented pharmaceutical products from India.

The amended stipulation will permit Indian companies to generate and export AIDS drugs to African and South East Asian countries. The Amendment has greatly broadened the scope of opposition to the patent by introducing two changes; that is after its publication but before its grant and after the grant, within one year.

As the large pharmaceutical companies in India are manufacturing the medicines and drugs from their own Original discovery and some other companies are manufacturing

the drugs through Reverse Engineered process, there is no need to stop their investment in Research and Development, till 2005. it is only the small pharmaceutical companies, who are producing drugs by copying from patented products, should think about the product patent.

TRIPS agreement is regarded by developing countries as having been forced upon them by the United States. This is not entirely a fair claim in the case of India, where the government and some of the successful generic drug companies recognized in the early 1990s that an eventual transition to a regime allowing pharmaceutical patent might be in the nation's long-term interest.

The TRIPS agreement, informed by both the classical arguments for patent and the developing country - argument, made a distinction among three classes of nation. Developed countries were required to bring patent regimes into immediate compliance with the agreement.

Developing countries, India and Brazil among them were given ten years, and the least developed countries, mostly those in Africa and the Middle East, were given more time.

This differentiated timetable makes sense for both developing and the least developed countries, and, specifically, for India.

Three factors may be suggested:

(1) India’s growing size in relation to markets

(2) Its increased capacity to innovate, and

(3) The flexibility inherent in the TRIPS agreement that will allow India to avoid most of the adverse consequences envisioned by the opponents of reform.

Let us discuss each of these factors in turn First, India’s rapid growth rate and it’s large and rapidly expanding middle class is likely to create a preference among some consumers for branded as opposed to generic that simply wasn't present in 1970.

Moreover, as the Indian market grows, the previously negligible effect of an Indian patent system on the incentives of foreign innovators becomes measurable. This incentive effect could be especially important in including foreign investment on drugs aimed at treating previously neglected diseases prevalent in India and similarly situated developing countries.

Second, even more significant than India's growing market is its increased capacity for indigenous innovation. India's largest pharmaceutical firms and some of its research institutes now have the scale, the trained personnel, and technical capacity to develop new

drugs, either alone or in partnership with foreign firms.

The availability of domestic patents, combined with low cost of performing research and development in India, could help to make India's largest pharmaceutical companies very successfully globally.

Moreover, a number of government Institute and private enterprises have developed the capacity to do large scale, highly cost-effective clinical trials. With product patent in place, India is likely become a major centre for "outsourced" clinical trials undertaken by the US and European pharmaceutical giants.

Without domestic, patent protection, neither India's potential for indigenous discovery nor its potential to become a leaning centre for clinical trials will be fully realized. Third, some of the adverse impacts feared by opponents of reforms are likely to be less severe than imagined, and other can be mitigated and other can be mitigated by effective use of the flexibility permitted under the recent Doha declaration.

The notion that drug prices and the overall cost of health care will skyrocket as a consequence of the government ordinance is exaggerated, because 90 per cent of the drugs currently classified by India as essential medicines are either unpatented or the patent has expired.

The prices of drugs patented before 1995 (including some of the most important anti-retroviral treatments for(HIV/AIDS) will not be affected, because these drugs will not be eligible for Indian patents and generic substitutes produced domestically are likely to continue to dominate the market.

It is true that those domestic producers that have been successful in copying foreign drugs without developing a capability for independent research are likely to be hurt, but the largest firms are likely to benefit from the opportunity that domestic patent protection will provide.

Finally, there is little substance to the concern that India’s conformity with TRIPS will seriously hamper the battle against the HIV/ AIDS pandemic in Africa and parts of Asia. Under the exception recently created during the Doha round, countries are free to impose compulsory licenses to deal with public Health emergencies and to export such drugs to countries lacking manufacturing facilities

The advent of WTO era coupled with the effectuating of the TRIPS agreements has indeed ushered in essence new horizons for the pharmaceutical industry in India and as an inevitable outcome, every player in the Industry ought to be geared up to face new endeavors in an arena of heightened regulation and competition. The management of

change under the new product patent regime is a reality that the Indian pharmaceutical industry ought to accept rather innocuously and nonchalantly. The management of change, especially when it is viewed within an increasingly regulated product patent regime, would inevitably throw up a lot of foreboding and even whilst these prospects have to be effectually handled, one ought to necessarily contemplate on the inherent aspects of the new product patent regime and thereafter devise perspicacious strategy for effectuating a comprehensive plan of action to face the new realities.

Jurisprudence, vis a vis, product patents, has been constantly evolving and the process has involved much ingenuity in developing the state of law as it is today from the state of flux in which it was not too long ago – the necessary outcome of much jurisprudential deliberation both by the legislatures and the courts have worked in cohesiveness to bring about the present stage. Wherein a platform has been created. That could eventually provide for a level playing field. The developing world should comprehend that plagiarizing pharmaceutical formulae tantamount to grand larceny under criminal law and as an inevitable outcome, a suit for un - liquidated damages can be maintained in action under the law of torts coupled with an inevitable contractual suits that might also be plausible. .

As a cardinal and primordial first step the Ministries responsible should first and foremost conduct relevant training for the Industry as a preventive first step towards familiarizing the average industry player. The fact of the matter is that in the WTO era that has been ushered in post the TRIPS agreements is essentially an era that would encapsulate free mobility of information and the norms that have standardized have necessary to be complied with in no uncertain terms. The issues pertain to compliance of regulations in terms of safeguarding patents across the globe, and Indian pharmaceutical companies have to effectuate a compliance regime wherein the norms are complied with in certitude, and more importantly, the court system should be thoroughly aggrandized to handle eventualities in the matter.

Compliance regulations are of crucial importance and as the WIPO increasingly monitors compliance issues, it is reckoned that pertinent issues are to be articulated in cogent terms in order to bring forth much alacrity with respect to compliance issues. Issues such as ever greening involving the patent term extension strategies and the sheer Implications of Compulsory Licensing provisions are to be cogently studied in detail:

The Prologue with the nearing of the TRIPS deadline, the pharmaceutical industry in India is gearing up to face new challenges. The product patent regime is no longer the challenge - it is a reality that the Indian pharma industry has accepted.

The new set of challenges stem from the deeper implications of the imminent product patent regime. With the exception of a few, most Indian pharma companies are unfamiliar with the nuances of complex patent prosecution strategies. The research-based pharmaceutical companies, on the other hand, have firsthand knowledge of successfully designing and implementing, sophisticated patent prosecution strategies. Therefore, the first hurdle for the Indian pharma industry is unevenness in the domain knowledge on patents. One of the ways to overcome this is to learn the use of patents as a business tool. The unrealistic defence against the global norms on patents is perhaps the most critical post-TRIPS challenge faced by the Indian pharmaceutical industry.

This section attempts to analyze the implications of the TRIPS compliant patent regime. The key issues taken up in this section are:

a) The scope and extent of patentability of pharmaceutical products;

b) Ever greening - the patent term extension strategies; and

c) Implications of Compulsory Licensing provisions.

Article 27 of the TRIPS Agreement harmonizes the subject matter of patent in a broad manner. However, the exclusions permitted under the TRIPS Agreement have created wide variance in the Indian Patent Act, 1970 ('the Act'). Complying verbatim with Article 27, Section 2(1)(j) of the Act provides that *'invention means a new product or process involving inventive step and capable of industrial application'*. Section 3 of the Act explicitly excludes certain categories of inventions from the scope of patentability. Critical categories include-plants, animals, parts of plants and/or animals, seeds, essentially biological processes, mathematical or business methods, computer program per se, inventions based on traditional knowledge, methods of treatment, diagnostic, therapeutic, and surgical methods.

Section 2(1)(j) and Section 3 are inextricably linked with each other; any addition in the latter would result in the constriction of the former. While Section 3 per se poses a direct conflict with the general mandate of Article 27 of the TRIPS Agreement, some of these restrictions can in fact stay on, provided they come under the general exceptions under the TRIPS, as provided in Art. 27 (2) and (3). One needs to closely watch the dialectics of Section 2(1) (j) and Section (3) of the Act in view of the substantive provisions contained in Art. 27(1) and the exceptions to patentability provided under Article 27(2) and (3) of the TRIPS Agreement.

A general reading of Section 2(1) (j) (which defines patentable inventions) with Section 3

of the Act (that provides the list of subject matters excluded from patentability) do not clearly indicate if it is possible to interpret these provisions to exclude certain aspects of pharmaceutical inventions from the scope of patentable subject matters. A section of the Indian pharma industry even today argues that a distinction has to be drawn between primary and secondary patents in the field of pharmaceutical inventions. According to them, primary patents are the ones directed at new molecules and secondary patents cover new combinations, optical isomers, active metabolites, polymorphs, 'prodrugs', new uses and so on. The question here is whether it is permissible under the TRIPS to draw such a distinction.

The Government of India seems to be adopting a balanced approach in addressing this issue. In the proposed Patent (Amendment) Bill, 2003, it is proposed to substitute the words "new use of known substance" with the words "mere new use of a known substance" in Section 3(d) of the Act. The interpretative scope of this is yet to be seen. It could eventually lead to the acceptability of 'Swiss-type' new use claims.

Understanding how things work, in terms of patents, and comprehending the opportunity it would provide Indian an entity is the quintessential first steps towards any meaningful articulation of patents with respect to the Indian Pharmaceutical Industry. Whilst one ought to readily envisage a harmonious construction in terms of interpretation of the TRIPS agreement whence it is read with the Indian Patents Act of 1970, it must necessarily as a corollary denote effectuating patent issues in a perspicacious manner in accordance with pragmatic approaches. As an elucidative reference, albeit in hypothetical terms, if one were to study the concomitant issues pertinent to Article 27 of the TRIPS agreements, and then if we were to juxtapose it with specific sections of the Indian Patents Act of 1970, one could readily decipher that whence construction of the relevant statues are done in a harmonious way, the effectuation, albeit subliminal, necessitates pragmatic solutions.

Nevertheless, the TRIPS agreements, as a standalone international agreement has inevitably provided for much interpretation and as a direct spin off much contumaciousness has inevitably followed in the developing world. Prudent research provides for handling he issues in a holistic manner for implementing agreements must go hand in hand … harmoniously with the average citizens' compulsions to comply with regulations in place. Much of the calumny of the recent past has been largely the result of unresearched verbose, and the need of the hour is clearly in the recognition of need to conduct awareness campaigns throughout much of the developing world, even whilst anti - trust laws have to

be innately be made efficacious. Countries like India should recognize the need to develop on patents indigenously and locally in order to benefit from inherent human capital advantages and as a rather innocuous commentary of the recent past we are yet to formulate a cogent policy for taking advantage of the new patent product regime as there are many opportunities or India primarily in research and in outsourcing Possibilities.[140]

The Act defines invention as denoting an invention of a new product or process that integrally is also capable of innate industrial application'. Section 3 of the Act explicitly excludes certain categories of inventions from the scope of patentability and these represent such critical areas like that of plants, animals, parts of plants and/or animals, seeds, essentially biological processes, mathematical or business methods, computer program per se, inventions based on traditional knowledge, methods of treatment, diagnostic, therapeutic, and surgical methods.

Quintessentially, Section 2(1)(j) and Section 3 are inextricably linked with each other And whilst Section 3 per se poses a direct conflict with the general mandate of Article 27 of the TRIPS Agreement, some of these restrictions can in fact stay on, provided they come under the general exceptions under the TRIPS, as provided in Art. 27 (2) and (3). Therefore the elemental issue lies in one requiring deciphering the language of Section 2(1) (j) and Section (3) of the Act in view of the substantive provisions contained in Art. 27(1) and the exceptions to patentability provided under Article 27(2) and (3) of the TRIPS Agreement.

The absolute basis of patents law rests in the fact that patents are granted only for an invention that ought to be new and useful. In the case of pharmaceutical products it is simply no different and the reward for the inventor is monopoly over the life of the patent which is 14 years in the case of product patent and 7 years in the case of process patents - however we are placed with an obligation of recognizing patent protection for a time horizon of 20 years under the provisions of the TRIPS agreement. The special protection provided for the pharmaceutical industry and earmarking them exclusively for process patents is really a departure from English law and as a matter of fact, the US Drug Corporations have for long been completely agitated over the rather slack patent protection in India - this is especially true because 'process patents' meant and encouraged 'reverse engineering' … and this could mean Manufacturing the same product under a different process. It is respectfully submitted that the relentless pressure from the US authorities has

[140] Sections 37 to 45 of the TM Act deal with the provisions of the assignment and transmission of the trade mark

brought forth amendments in our patent laws in 1999 and 2002 in order to provide for product patents in the pharmaceutical industry and to usher in exclusive marketing rights for five years from 1999.

The elemental definition of a patentable invention ought to readily provide an acceptable criteria that is intelligible and as a necessary corollary it ought to provide a cogent list that denotes patentable inventions and the core criteria in the determination ought to be centre around the novelty, utility and implementation criteria - the very blithe spirit of scientific ingenuity should in a sacrosanct way encapsulate the inherent ingenuity of the patentable invention. An antithetical stance by boorish western pharmaceutical companies has always to be anticipated as essentially the patents are granted for the scientific processes/ molecular dispensations inculcated in a process and the logical methodology ingrained as an inherent part of the process would necessarily entail the ingenuity much sought . Where the WIPO norms had to be read in to effectuate geographical indicators as an intrinsic issue. The postulates that go in to the making of the processes are of primordial significance and the aspects of scientific reasoning that perpetuate these pharmaceutical inventions have to be fostered with much alacrity as essentially these revolve around pristine thought processes that enunciate these pragmatic processes.

Ingenuity, is the name of the game, and formulations are necessarily a natural consequence of ingenuity - our research reckons that a general reading of Section 2(1) (j) (which defines patentable inventions) with Section 3 of the Act (that provides the list of subject matters excluded from patentability) do not clearly indicate if it is possible to interpret these provisions to exclude certain aspects of pharmaceutical inventions from the scope of patentable subject matters. Of core and critical importance to the Indian Pharmaceutical Industry is the major perceptive issue revolving a segmented approach towards primary and secondary inventions and the inevitable categorization eventually denotes that primary patents are the ones directed at new molecules and secondary patents are essentially the ones that cover new combinations, optical isomers, active metabolites, polymorphs, … etc ; The 64 $ question here is whether it is permissible under the TRIPS to draw such a distinction.

The Government of India has indeed promulgated an ordinance pertinent to the patents (third) amendment. ….. and as a matter of fact, it is only a culmination that was started on ten years ago. It is completely necessary to read into the ordinance along with the two amendments of 1999 and 2002 as India's patent Act always provided for process patent in

all fields and product patents in most fields albeit excluding Pharmaceuticals. In certitude, it fulfilled the legal obligations within time and as an inevitable outcome brought forth an equitable regime, vis a vis, Intellectual property norms juxtaposing public health as well - this is bound to help India unlock vast export markets even whilst it clinical research outsourcing and bio - technology would get a boost.

SUGGESTIONS

1. It is suggested that the pharmaceutical companies considerably raise their investments in R &D due to the introduction of product patents.
2. Pharmaceutical companies should create a sound infrastructure for undertaking or enhancing the research activities owing to the introduction of product patents.
3. It is suggested that small and medium pharmaceutical companies ensure good quality research, make sizeable investment in research, exports and up- gradation.
4. It is duty of the Government and the pharmaceutical companies to allay the fears of the common man regarding hike in drug prices.
5. It is suggested that the Government protects the interest of not only the common man but also the pharmaceutical companies in regard to product patents.
6. An important suggestion is that the Indian pharmaceutical companies take all out efforts possible to capture the drug market through good quality drugs at affordable prices through quality research work.
7. Product patent procedures and practices should be simplified and transparent to attract more companies to produce quality drugs at reasonable prices.
8. Separate intellectual property right cells should be created in all the pharmaceutical companies to deal with product patent related issues.
9. Network between the drugs controller General of India (DCGI) and the patent office must be a balanced one so that the position regarding issue, renewal and registration of patent can be known earlier.
10. More patent offices should be open for registration of patentable subject matters.

This article was initiated within intention to understand the pharmaceutical companies' long term orientation for survival and growth in the wake of WTO accord and the research & development initiatives. With the product patent being introduced from 2005, companies with clear vision and undertaking of the domestic and global markets will only be successful.

Hence the overall Indian has to transform its drug industry into a world class manufacture of

quality products on a sustainable scale of operation. The essence of future growth lies in its ability to innovate and introduce new products. If the Indian pharmaceutical industry has to emerge as a global competitor, the manufacturing and marketing innovation is the focus. Cost –reduction opportunities in manufacturing and marketing innovation through quality novel drugs and promotion will have to be concentrated. Companies that prepare for the future keeping the present in perspective will emerge as the survivors in the long-term.

The domestic market will be attractive due to the growing awareness of medical care, changing profile of diseases, rising per capita income and improving health infrastructure. Hence it is clear that the competition will only rise and the profit margins will be thin but the growth is guaranteed.

While the discussion in this article is confined to the above three issues that the Indian pharmaceutical companies face in the anvil of the new TRIPS compliant regime, the transition from a limited term process patent regime to the product patent regime can have several other far reaching implications. The impact of this transition will become evident in the years to come. In the meantime, the Indian pharmaceutical industry must gear up to face the challenges. Creation of a level playing ground is possible the moment the domain knowledge of patents is even among all the players in the Indian market place. To begin with, the efforts to achieve parity in knowing the rules of the game can be confined to India. But sooner or later the Indian pharmaceutical companies will have to transform into knowledge-based organizations capable of producing research-based medicine at prices affordable to the Indian people.